COMPLIANCE CAPSULE *with* IDFPR

Quarterly Newsletter

Illinois Department of Financial and Professional Regulation

SPRING 2023

USP 795 AND 797 UPDATES

Page 4

ALSO INSIDE:

CONTENTS

A NEWSLETTER FROM IDFPR FOR PHARMACY PROFESSIONALS

Welcome to the inaugural edition of our "Compliance Capsule" newsletter! The update will be published on the Department's Pharmacy webpage. A new edition will be published each quarter.

This year, we plan on further utilizing our pharmacy webpage, https://idfpr.illinois.gov/profs/pharm.asp, to better communicate with licensees. While updates will be provided via email blasts, we want to use our website to hear from you.

On our Pharmacy webpage, check out the email address listed under our new "Reporting" section. This email address, fpr.drugcomplianceunit@illinois.gov, will assist licensees to not only send required information to the Department, but also provide a more convenient method for you to maintain a record of the correspondence. The following are subjects that can be reported via the reporting tab:

- Departure PIC notification
- Pharmacy closing notification
- Remodel notification
- Change in operating hours
- DEA 106 reports
- Temporary pharmacy closure notice
- Employee termination reports

USP 795 AND 797 UPDATES

Final revised Compounding General Chapters <795> and <797> were finalized on November 1, 2022 and will become effective November 1, 2023. Those pharmacies performing non-sterile and sterile compounding should work on meeting the requirements of the updated chapter. The department understands the current compounding rules reference out of date revisions and editions and as such enforcement of the updates will not be initiated until updated rules with the most recent USP changes are published. The updates may are found at:

795: https://www.uspnf.com/notices/795-pub-announcement-20221101
797: https://www.uspnf.com/notices/797-pub-announcement-20221101

MOST FREQUENT VIOLATIONS

To help you avoid disciplinary action, here are some of the most frequent violations IDFPR sees of pharmacy licensees:

1) Failure of the departing PIC to notify the Department

1330.660 f) provides:
Within 30 days after a change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.

Departing PIC's please use the reporting tab on the website to report the change.

2) Failure of the pharmacist to provide patient counseling

1330.700 a) provides:
Upon receipt of a new or refill prescription, a prospective drug regimen review or drug utilization evaluation shall be performed. Prior to dispensing a prescription to a new patient, a new medication to an existing patient, or a medication that has had a change in the dose, strength, route of administration or directions for use, the pharmacist, or a student pharmacist directed and supervised by the pharmacist, shall provide verbal counseling to the patient or patient's agent on pertinent medication information. An offer to counsel shall be made on all other prescriptions.

3) Failure to provide adequate security in the pharmacy

3100.310 a) provides:
All applicants and licensees shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a person has provided effective controls against diversion, the Division shall use the security requirements set forth in this Section as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Division after evaluation of the overall security system and needs of the applicant or licensee

Please assure the CII cabinet is locked when not in use. Also, the pharmacy must be constructed with walls and doors to prevent public access to the pharmacy. During operating hours pharmacy doors must remain closed and not allowed to remain open or be rendered unsecure in any way.

(continued on page 6)

(continued from 5)

4) Not completing the Pharmacy Self-Inspection

1330.800 provides:
Every licensed pharmacy shall conduct an annual self-inspection using forms provided by the Division. The annual self-inspection shall be conducted during the same month, annually, as determined by the pharmacy. Documentation of the self-inspection shall be maintained at the pharmacy for 5 years. The primary objective of the self-inspection is to create an opportunity for a pharmacy to identify and correct areas of noncompliance with State and federal law. This includes, but is not limited to, recordkeeping, inventory, labeling and sanitation requirements.

Self-Inspections must be documented, once complete, to include the date completed and signature of the completing pharmacy employee. It is also required to complete a Self-Inspection for each pharmacy type performed (community, Institutional, compounding, ect.).

5) Failure to conduct an annual controlled substance inventory

3100.360 c) provides:
Every licensee shall conduct an annual inventory that includes an inventory with an actual count of the inventory on hand for all Schedule II Controlled Substances and an approximate inventory for all Schedule III, IV and V Controlled Substances. The inventory shall be maintained for a period of not less than 5 years.

The annual inventory must be completed no later than 12 months from the previous annual inventory.

6) Food or drink in the drug refrigerator/dispensing area

1330.630 e) provides:
Food and/or beverages shall only be placed in a designated area away from dispensing activities.

Please assure that a designated area, away from dispensing activities, is utilized to store or maintain any food or beverage

7) Failure to wear identification bearing name and designation

1330.30 k) provides:
Failing to keep one's self and one's apparel clean or to wear identification bearing name and designation.

While in the pharmacy each employee must be wearing an article that identifies their name and title (Pharmacist, Student Pharmacist, Technician, Certified Technician). Designations such as "cross trainer", "beauty consultant", or "store manager" do not meet the title requirement.

8) Failure to maintain an accurate log book for documenting Pharmacist rest/meal breaks

225 ILCS 85/15.1 (e) provides:
A pharmacy shall keep and maintain a complete and accurate record showing its pharmacists' daily break periods.

PHARMACY FREQUENTLY ASKED QUESTIONS AVAILABLE

The Department has Frequently Asked Questions (“FAQs”) available on our website: https://idfpr.illinois.gov/content/dam/soi/en/web/idfpr/faq/dpr/pharmacy-faq.pdf Please utilize this as a first source to answer any pharmacy-related question(s). If the answer to your question can not be found in the FAQ’s, please submit your inquiry to us by going here: fpr.drugcomplianceunit@illinois.gov. As the Department receives questions, they will be evaluated for addition to the FAQs.

DATA WAIVED PROGRAM

On December 29, 2022, with the signing of the Consolidated Appropriations Act of 2023 ("the Act"), Congress eliminated the DATA Waiver Program.

All DEA registrants should be aware of the following:

- A DATA-Waiver registration is no longer required to treat patients with buprenorphine for opioid use disorder.
- Going forward, all prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescription.
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.
- The Act does not impact existing state laws or regulations that may be applicable.

Illinois does not have regulations related to DATA-Waiver prescribing. Illinois pharmacies may fill buprenorphine prescriptions for opioid use disorder utilizing a standard DEA registration number.

MID-LEVEL PRACTICE PRESCRIPTIONS UPDATE (REQUIRED COLLABORATING PHYSICIAN SIGNATURES)

Title 68 1300.430 e) provides: The Advanced Practice Registered Nurse (“APRN”) shall sign his/her own name when writing and signing prescriptions. The collaborating physician’s or podiatric physician’s signature is not required.

There is no language in the Physician Assistant (“PA”) rules requiring the signature of the collaborating physician on prescriptions written by a PA.

2023 LEGISLATIVE UPDATE

The following is a summary of legislative updates from that became effective January 1, 2023 (unless otherwise documented):

225 ILCS 120/21 Provides:

Sec. 21. Reports to Department. Each licensee that is required to report suspicious orders under 21 USC 832 shall also submit such suspicions order reports to the Department.

225 ILCS 120/15 defines a suspicious order as:

"Suspicious order" includes, but is not limited to, an order of a controlled substance of unusual size, an order of a controlled substance deviating substantially from a normal pattern, and orders of controlled substances of unusual frequency as defined by 21 USC 802."

The Department requests that the suspicious order reports are submitted to the Department weekly in electronic format, preferably Excel spreadsheet. Only those orders to be shipped within or into the state of Illinois are required to be reported. No zero reports are required. Below is an example of how the reports should be labelled. Please note that each column should be labeled utilizing the reporting elements identified below and the labelled columns should be in the order as listed below. All reports should be sent to FPR.WDDReporting@Illinois.gov.

REPORTER DEA NO.	NDC NUMBER	QTY	UNIT CODE	PURCHASERS ILLINOIS LICENSE NO.	DEA ORDER FORM NO.	TRANSACTION DATE	STRENGTH	REASON CODE	REASON DESCRIPTION

Please direct all questions to Steven Smith Director, Drug Compliance at steven.smith@illinois.gov.

225 ILCS 85/43.5 Provides:

- In accordance with a standing order by a physician licensed to practice medicine in all its branches or the medical director of a county or local health department, a pharmacist may provide patients with prophylaxis drugs for human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis.

- A pharmacist may provide initial assessment and dispensing of prophylaxis drugs for human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis. If a patient's HIV test results are reactive, the pharmacist shall refer the patient to an appropriate health care professional or clinic. If the patient's HIV test results are nonreactive, the pharmacist may initiate human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis to eligible patients.

(continued on page 11)

(continued from page 10)

- The standing order must be consistent with the current version of the guidelines of the Centers for Disease Control and Prevention, guidelines of the United States Preventive Services Task Force, or generally recognized evidence-based clinical guidelines.

- A pharmacist must communicate the services provided under this Section to the patient and the patient's primary health care provider or other health care professional or clinic, if known. If there is no primary health care provider provided by the patient, then the pharmacist shall give the patient a list of primary health care providers, other health care professionals, and clinics in the area. The services provided under this Section shall be appropriately documented and retained in a confidential manner consistent with State HIV confidentiality requirements.

- The services provided under this Section shall take place in a private manner.

- A pharmacist shall complete an educational training program accredited by the Accreditation Council for Pharmacy Education and approved by the Department that is related to the initiation, dispensing, or administration of drugs, laboratory tests, assessments, referrals, and consultations for human immunodeficiency virus pre-exposure prophylaxis and human immunodeficiency virus post-exposure prophylaxis.

225 ILCS 85/9 (a) Provides:

- A registered pharmacy technician may be delegated to perform any task within the practice of pharmacy if specifically trained for that task, except for patient counseling, drug regimen review, clinical conflict resolution, or final prescription verification except where a registered certified pharmacy technician verifies a prescription dispensed by another pharmacy technician using technology-assisted medication verification.

- A registered pharmacy technician may be delegated to perform any task within the practice of pharmacy if specifically trained for that task, except for patient counseling, drug regimen review, clinical conflict resolution, or providing patients prophylaxis drugs for human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis.

- A registered pharmacy technician may be delegated to perform any task within the practice of pharmacy if specifically trained for that task, except for patient counseling, drug regimen review, or clinical conflict resolution.

225 ILCS 85/25.10 Provides:

- Nothing in this Section shall prohibit an individual employee licensed as a pharmacist, PHARMACY TECHNICIAN OR STUDENT PHARMACIST from accessing the employer pharmacy's database from a pharmacist's home or other remote location or pharmacist's home verification for the purpose of performing certain prescription processing functions, provided that the pharmacy establishes controls to protect the privacy and security of confidential records.

225 ILCS 85/35.21 (a) Provides:

- The Department may issue citations to any licensee for any violation of this Act or the rules. The citation shall be issued to the licensee or other person alleged to have committed one or more violations and shall contain the licensee's or other person's name and address, the licensee's license number, if any, a brief factual statement, the Sections of this Act or the rules allegedly violated, and the penalty imposed, which shall not exceed **$3,000**.

225 ILCS 85/43 (Effective 5-13-2022) Provides:

- The dispensing of hormonal contraceptives to a patient shall be pursuant to a valid prescription or standing order by a physician licensed to practice medicine in all its branches or the medical director of a local health department, pursuant to the following:

(continued on page 12)

(continued from page 11)

- A pharmacist may dispense no more than a 12-month supply of hormonal contraceptives to a patient

- A pharmacist must complete an educational training program accredited by the Accreditation Council for Pharmacy Education and approved by the Department that is related to the patient self-screening risk assessment, patient assessment contraceptive counseling and education, and dispensation of hormonal contraceptives

- A pharmacist shall have the patient complete the self-screening risk assessment tool; the self-screening risk assessment tool is to be based on the most current version of the United States Medical Eligibility Criteria for Contraceptive Use published by the federal Centers for Disease Control and Prevention;

- Based upon the results of the self-screening risk assessment and the patient assessment, the pharmacist shall use his or her professional and clinical judgment as to when a patient should be referred to the patient's physician or another health care provider;

- A pharmacist shall provide, during the patient assessment and consultation, counseling and education about all methods of contraception, including methods not covered under the standing order, and their proper use and effectiveness;

- The patient consultation shall take place in a private manner; and

- A pharmacist and pharmacy must maintain appropriate records.

- Nothing in this Section shall be interpreted to require a pharmacist to dispense hormonal contraception under a standing order issued by a physician licensed to practice medicine in all its branches or the medical director of a local health department.

NOTE The Illinois Department of Public Health is currently working on the Standing Order. When complete, the Standing Order, along with other related documents will be posted on the Departments website

225 ILCS 19.1 Provides:

- Due to the recent rise in opioid-related deaths in Illinois and the existence of an opioid antagonist that can reverse the deadly effects of overdose, the General Assembly finds that in order to avoid further loss where possible, it is responsible to allow greater access of such an antagonist to those populations at risk of overdose.

- Notwithstanding any general or special law to the contrary, a licensed pharmacist shall dispense an opioid antagonist in accordance with written, standardized procedures or protocols developed by the Department with the Department of Public Health and the Department of Human Services and filed at the pharmacy before implementation and are available to the Department upon request.

- Before dispensing an opioid, a pharmacist shall inform patients that opioids are addictive and offer to dispense an opioid antagonist.

- For the purpose of this Section, "opioid antagonist" means a drug that binds to opioid receptors and blocks or inhibits the effect of opioids acting on those receptors, including, but not limited to, naloxone hydrochloride or any other similarly acting and equally safe drug approved by the U.S. Food and Drug Administration for the treatment of drug overdose.

(continued on page 13)

(continued from page 12)

225 ILCS 85/16 Provides:

- If a pharmacy temporarily closes for more than 72 hours, it is the duty of the pharmacist in charge and the owner of such pharmacy to report to the Department within 72 hours of temporary closure of a pharmacy. The closing pharmacy must post signage and provide notification to customers

720 ILCS 570/311.6 (Effective 1/1/2024) Provides:

- Notwithstanding any other provision of law, a prescription for a substance classified in Schedule II, III, IV, or V must be sent electronically, in accordance with Section 316. Prescriptions sent in accordance with this subsection (a) must be accepted by the dispenser in electronic format.

- Notwithstanding any other provision of this Section or any other provision of law, a prescriber shall not be required to issue prescriptions electronically if he or she certifies to the Department of Financial and Professional Regulation that he or she will not issue more than 25 prescriptions during a 12-month period. Prescriptions in both oral and written form for controlled substances shall be included in determining whether the prescriber will reach the limit of 25 prescriptions.

- The Department of Financial and Professional Regulation shall adopt rules for the administration of this Section. These rules shall provide for the implementation of any such exemption to the requirements under this Section that the Department of Financial and Professional Regulation may deem appropriate, including the exemption provided for in subsection (b).

NOTE 720 ILCS 570/311.6 had an initial effective date of 1/1/2023. The effective date has been updated to 1/1/2024.

105 ILCS 5/22-30 f) Provides:

The school district, public school, charter school, or nonpublic school may maintain a supply of asthma medication in any secure location that is accessible before, during, or after school where a person is most at risk, including, but not limited to, a classroom or the nurse's office. A physician, a physician assistant who has prescriptive authority under Section 7.5 of the Physician Assistant Practice Act of 1987, or an advanced practice registered nurse who has prescriptive authority under Section 65-40 of the Nurse Practice Act may prescribe undesignated asthma medication in the name of the school district, public school, charter school, or nonpublic school to be maintained for use when necessary. Any supply of undesignated asthma medication must be maintained in accordance with the manufacturer's instructions.

CONTACT US

Have questions about Pharmacy professions in Illinois? Contact us by going here:

https://idfpr.illinois.gov/profs/email/prfgrp10.html